

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
For Abbott Aeroset Phenytoin Assay**

**1. Manufacturer and Contact Information:**

Manufacturer: Syva Company  
3403 Yerba Buena Rd.  
P.O. Box 49013  
San Jose, CA 95161-9013

Abbott Laboratories  
820 Mission Street  
South Pasadena, CA 91030

Distributor: Abbott Laboratories  
K-Complex  
Route 41 & Martin Luther King Drive  
North Chicago, IL 60064

Contact Information: Paul Rogers  
Syva Company  
3403 Yerba Buena Road  
San Jose, CA 95161-9013  
Tel: 408-239-2000

**2. Device Classification Name:**

The Clinical Chemistry and Clinical Toxicology Devices Panel have classified "Diphenylhydantoin Test System" as Class II. Reference: 21 CFR 862.3650, revised April 1, 1993.

**3. Intended Use:**

Abbott Aeroset® Phenytoin Assay is a homogeneous enzyme immunoassay. The assay is intended for use in the quantitative analysis of phenytoin in human serum or plasma.

**4. Device Description and Characteristics:**

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Syva Company is submitting the Premarket Notification, 510(k) on behalf of Abbott Laboratories to convey Abbott's intention to commercially market an *in vitro* diagnostic reagent test kit for the analysis of Phenytoin in human serum or plasma. The Abbott Aeroset® Phenytoin Assay is a homogenous enzyme assay intended for use in quantitative analysis of Phenytoin in human serum or plasma. The Abbott Aeroset® Phenytoin Assay and calibrators has been found to be equivalent to the predicate device: Emit® 2000 Phenytoin Assay (K913429) with regard to intended use, assay sample, and overall performance characteristics.

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**For Abbott Aeroset Phenytoin Assay (cont.)**

Comparative Analysis: The Abbott Aeroset Phenytoin Assay and calibrators showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in a correlation of 1.0 with a slope value of 1.04.

Precision: A Precision study was performed and the Abbott Aeroset Phenytoin Assay demonstrated acceptable within-run precision with coefficients of variation (%CV) ranging from 1.67 to 1.83% and acceptable total precision with coefficients of variation (%CV) ranging from 2.82 to 3.54%.

**5. Substantial Equivalence:**

In conclusion, Abbott Laboratories considers the Abbott Aeroset Phenytoin Assay and Abbott Aeroset Phenytoin Calibrators to be substantially equivalent to the Emit 2000 Phenytoin Assay(K913429) and Emit 2000 Phenytoin Calibrators(K913429) with regard to intended use, assay sample, and overall performance characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 27 2000

Ms. Mary Beth Femmel  
Regulatory Affairs  
Syva Company – Regulatory Affairs  
3403 Yerba Buena Road  
P.O. Box 49013  
San Jose, California 95161-9013

Re: K993026  
Trade Name: Abbott Aeroset® Phenytoin Assay  
Abbott Aeroset® Phenytoin Calibrators  
Regulatory Class: II  
Product Code: DIP  
Dated: January 10, 2000  
Received: January 11, 2000

Dear Ms. Femmel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

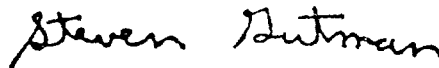
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): K993026

Device Name: Abbott Aeroset® Phenytoin Assay  
Abbott Aeroset® Phenytoin Calibrators

**Indications for Use:**

The Abbott Aeroset® Phenytoin Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of phenytoin in human serum or plasma on the Abbott Aeroset® analyzer (K980367). Monitoring serum phenytoin concentrations, along with careful clinical assessment, is the most effective means of improving seizure control, reducing the risk of toxicity, and minimizing the need for additional anti-convulsant medication for the following reasons:

- Serum phenytoin concentrations correlate better with pharmacologic activity than does dosage because of individual differences in absorption, metabolism, disease states, concomitant medication, and compliance. Serum concentration monitoring helps physicians individualize dosage regimens.
- The hepatic enzyme system for metabolizing phenytoin can become saturated within the drug's therapeutic range. When this occurs, small dosage alterations can lead to unexpected drug accumulation and clinical toxicity.
- Phenytoin is safe and effective only in a narrow range of serum concentrations.
- Methods historically used to monitor serum phenytoin concentrations include chromatographic assays and immunoassays.

Dean Cohen  
(Division Sign-Off)

Division of Clinical Laboratory Devices

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510(k) Number K993026

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)